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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,

Plaintiff,

v.

CORERX, INC.,

Defendant.

Case No. 1:21-cv-10656

PUBLIC REDACTED VERSION

DECLARATION OF VENKAT KRISHNAN
IN SUPPORT OF PLAINTIFF BIONPHARMA INC.'S
MOTION FOR PRELIMINARY INJUNCTION

I, Venkat Krishnan, declare as follow:

1. I am the President and Chief Executive Officer of Bionpharma Inc. I have held this position since Bionpharma was formed in November 2014. My responsibilities include oversight of all aspects of Bionpharma's business, ranging from the sourcing of raw materials for use in the manufacture of pharmaceutical products, identification and negotiation with partner manufacturers, and sales and distribution of Bionpharma's products. I have worked in the generic pharmaceutical industry since 1997, and thus had approximately 17 years of experience in this industry prior to joining Bionpharma.

2. I submit this Declaration in support of Bionpharma's Motion for a Preliminary Injunction.

3. I have personal knowledge of the following facts and, if called to testify, I could and would testify competently to the matters stated herein.

4. Bionpharma is a generic pharmaceutical company, founded in 2014 to develop and commercialize affordable, quality generic drugs. Bionpharma's business model is to partner with pharmaceutical manufacturers; Bionpharma will maintain responsibility for sourcing active ingredients, regulatory approval of the drug product, and sales and distribution of the drug product. These products are approved for commercial marketing in the United States under abbreviated new drug applications submitted to the FDA by Bionpharma, and distributed under the Bionpharma label.

Bionpharma's Product and Relationship with CoreRx

5. In August 2018, Bionpharma submitted Abbreviated New Drug Application ("ANDA") No. 212408 ("Bionpharma's ANDA") to the FDA, seeking regulatory approval to market a enalapril maleate oral solution product (Bionpharma's "Product"), generic to

the branded product Epaned. Prior to submission of its ANDA, Bionpharma engaged CoreRx to perform the research and development of Bionpharma's Product. Specifically, CoreRx was contracted to develop a formulation for Bionpharma's Product that would not infringe patents owned by the brand drug owner, Silvergate Pharmaceuticals (now Azurity Pharmaceuticals).

6. Bionpharma also engaged CoreRx to manufacture Bionpharma's Product for commercial sale once Bionpharma obtained final regulatory approval from the FDA. Bionpharma and CoreRx executed a Master Manufacturing Supply Agreement (the "Agreement") concerning Bionpharma's Product in November 2020. A true and correct copy of the Agreement is attached hereto as **Exhibit F**. In the Agreement, Bionpharma and CoreRx agreed to a transfer price of [redacted].

Azurity and its Predecessors Engaged in Extensive Litigation to Prevent Bionpharma from Launching its Product

7. In December 2018, Silvergate sued Bionpharma in the U.S. District Court for the District of Delaware, alleging that Bionpharma's Product infringed several of Silvergate's patents.[1] That case went to trial, and in April 2021; the district court subsequently ruled that Bionpharma's Product did not infringe. Bionpharma expended substantial resources for a company of its size in developing a unique, non-infringing generic pharmaceutical product, and successfully litigating against the brand drug owner's patents. Bionpharma was the first company to successfully file for approval to market a generic version of Epaned and successfully challenge the patents purportedly covering that product, and therefore was awarded 180 days of exclusivity during which FDA could not

[1] *Silvergate Pharms., Inc. v. Bionpharma Inc.*, 2021 WL 1751148 (D. Del., April 29, 2021).

approve any other ANDA for a generic Epaned product. This achievement provides Bionpharma an opportunity to generate substantial revenue in selling the only generic enalapril oral solution product for this period, and also bolster's Bionpharma's industry reputation, showing customers that Bionpharma is highly innovative and determined to achieve its goals.

8. Having won that lawsuit, Bionpharma commercially launched its Product in August 17, 2021.

9. In June 2019, September 2020, June 2021, and October 2021, Azurity brought additional patent infringement suits against Bionpharma regarding Bionpharma's Product, and in one of those cases, sought an injunction to force Bionpharma to withdraw its Product from the market and cease selling any new Product.[2] That injunction was denied.[3]

10. In October 2021, Azurity further brought patent infringement lawsuits against CoreRx, accusing CoreRx of infringing the same patents Azurity asserted against Binopharma, on account of CoreRx's manufacturing of Bionpharma's Product.[4]

CoreRx's Escalating Demands and Breach

11. Upon becoming aware of Azurity's lawsuits against CoreRx, Bionpharma immediately offered to indemnify CoreRx under the Agreement. Going beyond what was reasonably required by the Agreement, Bionpharma also offered to help pay for separate

[2] *Silvergate Pharms., Inc. v. Bionpharma Inc.*, 1:19-cv-01067 (D. Del.); *Silvergate Pharms., Inc. v. Bionpharma Inc.*, 1:20-cv-01256 (D. Del.); *Azurity Pharms., Inc. f/k/a CutisPharma, Inc. v. Bionpharma Inc.*, 3:21-cv-12870 (D.N.J.); *Azurity Pharms., Inc. v. Bionpharma Inc.*, 1:21-cv-01455 (D. Del.).
[3] *Azurity Pharms., Inc. v. Bionpharma Inc.*, 21-cv-01286-LPS (D. Del. Nov. 10, 2021)
[4] *Azurity Pharms., Inc. v. CoreRx, Inc.*, 1:21-cv-01522 (D. Del.); *Azurity Pharms., Inc. v. CoreRx, Inc.*, 8:21-cv-02515 (M.D. Fla.).

counsel (the Buchanan Ingersoll firm) that CoreRx wanted to retain in addition to counsel provided by Bionpharma (the Fox Rothschild firm). A true and correct copy of correspondence from Bionpharma to CoreRx offering a full indemnity in these cases is attached hereto as **Exhibit G**. At my direction, Bionpharma's counsel negotiated with CoreRx to attempt to reach an agreement for Bionpharma to fully defend CoreRx in these litigations at Bionpharma's expense.

12. On or about November 26, 2021, Azurity voluntarily dismissed its complaints against CoreRx. True and correct copies of the dismissals are attached hereto as **Exhibit H**.

13. On November 19, 2021, CoreRx sent to Bionpharma a letter discussing pricing for products manufactured by CoreRx for Bionpharma. A true and correct copy of this letter is attached hereto as **Exhibit I**. In this letter, CoreRx stated that it intended to change the transfer price of several products including Bionpharma's Product; specifically, CoreRx demanded to more than double the price, *i.e.*, to take it from [redacted] to [redacted]. This represents an increase of [redacted], more than doubling the cost to Bionpharma. This letter also disclosed that the cost of enalapril active ingredient to be purchased by CoreRx had not increased since the Agreement was entered into in November 2020. Specifically, the cost to CoreRx remained constant: [redacted].

14. Bionpharma responded to CoreRx's letter, stating that the "Agreement provides that the Transfer Price is 'the price agreed by the Parties' as specified in the attachment ([redacted]), and can be 'mutually amended from time to time.' There is no provision for CoreRx to unilaterally take a price increase, and the information CoreRx provided shows that the API cost remains unchanged." A true and correct copy of

Bionpharma's letter to CoreRx is attached hereto as **Exhibit J**. Bionpharma proposed in that letter that the price of the products (including Bionpharma's Product) remain the same as the previous year. CoreRx has responded by providing additional information regarding costs, but no revised pricing.

15. Since a new CEO of CoreRx (Ajay Damani) took over management in October 2021, CoreRx has complained to Bionpharma that CoreRx was not making enough money on the products it sold to Bionpharma.

16. On November 30, CoreRx sent a facsimile message to Bionpharma stating that "as of December 1, 2021, CoreRx will be unable to supply enalapril maleate for Bion's Epaned product. In accordance with Section 5.11 of the Master Manufacturing Supply Agreement that addresses Supply Interruptions, CoreRx will work with Bion to secure an alternative source of supply for this product." A true and correct copy of this correspondence is attached hereto as **Exhibit K**.

17. Section 5.11 of the Agreement concerns supply interruptions; that is, inability to supply product. Typical reasons for this include unavailability of key raw materials or equipment failures at the manufacturing site. Section 5.11 was never intended to permit CoreRx to unilaterally decide that it simply did not wish to supply Product to Bionpharma in the middle of the Agreement's term (which runs to [redacted]).

18. Bionpharma responded to CoreRx's fax on December 1, noting that CoreRx had not provided the reason for its purported inability to supply Product. A true and correct copy of Bionpharma's response is attached hereto as **Exhibit L**. Bionpharma's response further advised CoreRx that CoreRx was in breach of the Agreement.

19. Bionpharma has performed all of its duties and obligations under the Agreement, and has not breached it in any way. Indeed, in many ways such as agreeing to fund separate counsel of CoreRx's own choice for the lawsuits brought by Azurity, Bionpharma has gone above and beyond its written obligations.

20. Last week, a major customer told Bionpharma that it was concerned about Bionpharma's ability to keep supplying Product, because it had been hearing rumors of an upcoming supply interruption or quality problem. As set forth in the Declaration of Iltifat Hassan, upon hearing of such rumors, Bionpharma's Vice President -- Quality, Iltifat Hassan, placed a telephone call to CoreRx's Director of Quality Control, Eric Primelles, who stated to Mr. Hasan that there were no issues with Product quality.

21. On December 7, 2021, Bionpharma and CoreRx met by teleconference with their respective counsel present. I asked CoreRx to explain the nature of the purported supply interruption. CoreRx responded through its counsel, Rajiv Khanna of Buchanan Ingersoll & Rooney PC, that the contract did not require CoreRx to provide any explanation, and that it would not give the reason.

22. I asked if the purported supply interruption had anything to do with a quality problem, because that would be a serious matter for a pharmaceutical, and CoreRx had an obligation to let Bionpharma know of any quality problems right away under both the Agreement and under the Parties' separate quality agreement. CoreRx again refused to answer. I said that we assumed in that case that there were no quality problems. Attorney Khanna said "you can assume anything you want." I referred to Mr. Hasan's call with Eric Primelles, CoreRx's Director of Quality Control, who had assured Mr. Hasan that there was no quality problem. Attorney Khanna replied "that's hearsay." I raised with CoreRx's

management CoreRx's statement to a Bionpharma employee that a decision to no longer supply Product to Bionpharma was made by CoreRx's management, and again received no substantive response.

23. I asked if CoreRx would at least deliver the balance of the pending order due for December delivery. CoreRx refused, and said it had already told us that it would not deliver the Product. I asked how long the supply interruption would last. CoreRx would not give this information.

CoreRx's Breach Irreparably Harms Bionpharma's Business Relationships, Goodwill, and Reputation

24. Bionpharma last placed a Firm Order, which under the Agreement CoreRx must accept and cannot cancel or revise, on August 26, 2021 for [redacted] of Product by way of Purchase Order No. PO4500001497. A true and correct copy of Purchase Order No. PO4500001497 is attached hereto as **Exhibit M**. To date, CoreRx has shipped [redacted] of Product purchased pursuant to that order, leaving [redacted] outstanding. CoreRx has informed Bionpharma that this Product will never be delivered. On December 3, 2021, Bionpharma placed another Firm Order for [redacted] of Product pursuant to Purchase Order No. PO4500001835. A true and correct copy of Purchase Order No. PO4500001835 is attached hereto as **Exhibit N**.

25. Bionpharma's customers have ordered, and Bionpharma has delivered [redacted] of Product to date. Bionpharma received a purchase order from a customer for an additional [redacted] of Product, which Bionpharma was forced to turn down, knowing that it would be unable to fulfill this order due to CoreRx's conduct.

26. Bionpharma's reputation and goodwill is further bolstered by its position as the sole distributor of generic Product. Bionpharma has made inroads with new and

existing customers for products above and beyond Product by virtue of its unique ability to supply this Product.

27. Bionpharma's reputation in the industry is that of an innovative and reliable distributor of generic pharmaceutical products.

28. The generic pharmaceutical industry is small and highly competitive. In bidding for sales contracts, competing distributors' products are often priced identically, or within a few cents per unit differently. Because of the negligible cost differences between distributors competing for sales, whether or not a distributor secures a sale with one of the major purchasers of generic drug products is largely based on existing business relationships and industry reputation.

29. In this particular case, customers who have generally not purchased significant quantities of products from Bionpharma turned to Bionpharma to obtain generic Product for their end-user customers. These Product sales have increased Bionpharma's industry reputation and created new and strengthened business relationships with those purchasers.

30. A sudden failure to fulfil its customers' orders for Product will reverse any gains made by Bionpharma and will drive its customers to seek to purchase their generic pharmaceutical products from any other of Bionpharma's competitors. Failure to deliver product as ordered is one of the most reputationally damaging events that a generic pharmaceutical distributor could endure. Bionpharma's customers will not tolerate unfulfilled purchases, as they will experience backlash from their own customers. Alternatively, Bionpharma's customers will continue to sell Product to their end-user customers at the same price, but will be forced to buy it from the brand manufacturer,

Azurity, at greatly increased cost. In either event, Bionpharma's customers stand to lose revenue and goodwill of their own, and will certainly blame Bionpharma for this.

31. Additionally, Bionpharma has entered into contracts with several customers for continued supply of its Product. These contracts require that Bionpharma provide notice of supply failure, and to pay penalties in the event it is unable to meet its obligations to provide Product to its customers. If CoreRx's breaching conduct continues, Bionpharma will be in breach of its own contractual obligations to its customers, irreversibly damaging its reputation and goodwill. Bionpharma will further need to provide notice to the FDA of an interruption of the manufacture of the Product likely to lead to a meaningful disruption in the supply of enalapril maleate oral solution pursuant to Section 506C(a) of the Federal Food, Drug, and Cosmetic Act.

32. Furthermore, without this unique product, Bionpharma will lack a distinguishing product to even get in the door with major purchasers of generic pharmaceutical products. In view of the generic drug industry as a whole, Bionpharma is very small compared to generic players such as Teva, Sandoz, and Mylan. Bionpharma needs to be highly innovative to compete with those companies, and products like Bionpharma's Product are the lifeblood of Bionpharma's future success.

33. Bionpharma will be irreparably harmed because of CoreRx's conduct in suddenly cutting off supply of Product to Bionpharma. Bionpharma will face devastating loss of reputation and goodwill to its customers, who will turn to other distributors with reputations for reliability when making their own purchasing decisions. Bionpharma will further lose the most unique product in its catalog, one that drives sales far beyond its own

value by giving Bionpharma inroads to major customers and providing opportunities for Bionpharma to sell its other product.

34. It will cost Bionpharma hundreds of thousands of dollars, and take at minimum nine months to identify and bring online an alternate source of Product. Additionally, many of the raw materials needed to manufacture and package the product are not readily available. The new manufacturer must have an FDA-qualified manufacturing site for liquid-dose products. The tech transfer process is also fraught with risk; if new manufacturer's test batches do not meet all quality standards, the transfer process must be scrapped and re-started. Once test batches are successfully made, those batches must be set aside for several months of stability studies. Bionpharma is currently engaged in attempting to transfer the product as soon as possible, but there is a struggle to get the raw materials required for preliminary testing. After repeated requests, Bionpharma was able to obtain from CoreRx small quantities of the enalapril active ingredient and certain other raw materials (but not all) for this preliminary testing by potential new manufacturers of the product. Attached hereto as **Exhibit O** is a true and correct copy of email correspondence between Bionpharma and CoreRx concerning transfer samples of these raw materials. Nevertheless, these emails clearly show that CoreRx retains far more raw material than it needs to manufacture the Product should this injunction be entered, and it is going to take a long time for Bionpharma to identify an acceptable new manufacturer for the Product before initiating the transfer.

The Public Benefits from Bionpharma's Product and is Harmed by CoreRx's Breach

35. As with enalapril tablets, a product approved decades ago, Bionpharma's Product is indicated for the treatment of cardiac conditions. However, many children also

suffer from these conditions, such as hypertension, but have difficulty taking medication as tablets. Bionpharma's Product is formulated as an oral liquid, and this makes it much easier to use for children suffering from such conditions. As such, children are the primary patients using of Bionpharma's Product.

36. I understand that the retail price of Bionpharma's Product is substantially lower than that of Epaned. I further understand that most patients will pay substantially less for Bionpharma's Product compared to Epaned because most major prescription drug insurers cover the cost of generic drug products for very low patient co-pay. For example, a typical co-pay for an insured patient purchasing generic medication would be $5 or $10. Coverage for branded products is often far less robust, leaving patients to pay a higher percentage of the higher retail price, and therefore a much higher total amount.

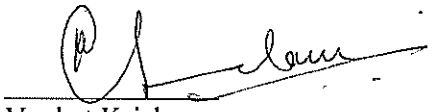
37. When generic version of a drug product is available, most prescription drug insurers designate the generic as the preferred product, and will either provide no coverage for the branded product or potentially coverage only with a much higher patient copay or with prior authorization from the prescribing physician. If, because of this supply interruption from CoreRx, Bionpharma is unable to satisfy the demand nationwide for the Product, the Product will start becoming unavailable on a patchwork basis from pharmacy to pharmacy. For example, one pharmacy chain may still have the Product in stock, but only at some of its locations. A different pharmacy chain as well as many independent local pharmacies may have no inventory at all. Similarly, one distributor/wholesaler may have Product in its inventory to supply to pharmacies, while another distributor/wholesaler may have run out. The result as indicated above is a unpredictable patchwork of Product being available at some pharmacies but not at others.

38. Prescription drug insurers do not adjust their coverage in real time. Accordingly, if there is a shortage of Product caused by the supply interruption from CoreRx, the prescription drug insurers will not automatically or quickly resume providing coverage for the branded product Epaned. The result is that a patient, or more likely, the patient's parent, will face the situation at the pharmacy that the pharmacist cannot fill the prescription with the Product because it is out of stock, but the patient's insurance will not cover the branded product Epaned. If the customer is unable to pay the uninsured cash price for Epaned, he or she will not be able to have the prescription filled. The customer could potentially seek out other pharmacies to find one that accepts the patient's insurance and has the generic product in stock, but this can be difficult depending in part on how many pharmacies are within the patient's vicinity. This situation will exacerbate as supply of Product continues to dwindle nationwide.

39. Adding to the difficulty is the fact that most prescriptions are provided electronically to a specific pharmacy identified by the patient to the prescribing physician. There is not, with this system, the familiar paper prescription that the patient can bring to any pharmacy of their choosing. For example, if the patient's prescription was sent electronically to one pharmacy, but that pharmacy is out of stock of Product, and the patient seeks out another pharmacy, that other pharmacy, even if it does have Product in stock, will not have the patient's prescription. This would require the patient to either seek a new prescription from the prescribing physician to be sent to the pharmacy with in-stock Product, or to try to get the original pharmacy to transfer the electronic prescription. Both of these can be challenging and time consuming, again with the result that the patient may not be able to secure a refill of his or her prescription before running out.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated: December 13, 2021



Venkat Krishnan